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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MAHAFKEY, KELLY JO

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,461

Applicant(s)

STAWSKI ET AL.

Examiner

Kelly Mahafkey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 22-29,32 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21,30,31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/30/04 & 10/29/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21, 30, 31, and 33-36, drawn to a hard candy, classified in class 426, subclass 89.
 - II. Claims 22-28, drawn to method of making a hard candy, classified in class 426, subclass 658.
 - III. Claims 29, 32, and 37, drawn to a method of making a hard candy, classified in class 426, subclass 512.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process; an outer hard candy shell could be in the shape of a box and an another, narrow, hard candy could be inserted into the hard candy box shell, therefore forming a jacketed hard candy.
4. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process; the inner and outer shells of the hard candy could be formed by mixing one sweetened mass with a second sweetened mass that possessed a different cooling rate, and therefore form a jacketed hard candy.

5. Inventions II and III are independent species. It can be shown that the species under the genus method of making hard candies, are independent. Invention II is classified in a species in which the hard candy is made by combining multiple ingredients to form an inner and outer shell, treating them together, and thus forming a multilayered hard candy. Invention III is classified in a species in which the hard candy is made by combining multiple ingredients, separating those ingredients into an inner and outer shell compositions, treating those compositions individually, forming two individual hard candies, and then combining those hard candies to form a multilayered hard candy.

6. Because these inventions (I, II, and III) are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Steven Shurtz on November 2, 2005 a provisional election was made with traverse to prosecute the invention of the candy, claims 1-21, 30, 31, and 33-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-29, 32, and 37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-20, 30, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanke (WO 97/06695).

10. Regarding claim 1, Hanke teaches of a boiled hard candy product that includes two distinct and discrete regions, a coolant and flavor region that can be in various forms, including the form as hard candy. Refer specifically to Abstract, Page 3 Paragraph 3, Page 8 Paragraph 1, and Page 10 Paragraph 3. Hanke discloses (Page 3 Paragraphs 3 and 4) that the outer coating or jacket may be continuous and can be comprised of the coolant composition, enrobes the flavor composition or the core to create a centre-filled candy. Hanke discloses that the coolant composition or jacket contains 0.01-15%, preferably 0.5-10% of the cooling agent and minor levels of flavoring ingredients (Page 7 Paragraphs 3 and 4, Page 8 Paragraph 1). Hanke discloses that the flavor composition contains preferably 0.4-1.5% flavoring and trace amounts of cooling agents (Page 10 Paragraphs 2 and 3). Hanke, therefore, teaches that the level of cooling agents in the jacketed or outer layer is greater than the level of cooling agents in the core.

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11. Regarding claims 2 and 3, Hanke teaches that the coolant composition or outer layer comprises 5-15% of the composition and therefore, the core containing the flavoring comprising 85-95% of the composition (Page 13 Paragraph 3).

12. Regarding claim 4, Hanke teaches that the carrier composition which is utilized to add flavoring and cooling agents is typically of the same form and composition prior to the addition of one or more flavoring and cooling agents (Paragraph 10 Page 3).

13. Regarding claim 5, Hanke discloses that the jacket or coolant composition can comprise 0.1-0.15% of the cooling agent which can include menthol (Page 1 Paragraph 2 and Page 8 Paragraph 2).

14. Regarding claim 6, specifically the range of 0.4-2%, Hanke discloses that the product amount of flavoring agent employed is normally a matter of preference subject to factors such as flavor type, base type, and strength desired (Page 10 Paragraph 3). Hanke teaches that it is preferred for the flavoring composition to contain 0.4-1.5% of the flavoring agents and the jacket or coolant composition contains minor levels of flavoring agents (Page 8 Paragraph 1).

15. Regarding claim 7, specifically the range of 0.5-1%, Hanke discloses that the coolant composition or jacket contains preferably 0.5-10% of the cooling agent and that the flavor composition contains trace amounts of cooling agents (Page 10 Paragraph 2 and Page 7 Paragraph 3).

16. Regarding claims 8-11, (Page 8 Paragraph 1) Hanke teaches that the carriers are chosen based upon the particular form that the confectionary products take. Hanke teaches that the confectionary product's base that is used to make both the jacket and

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the core can be sugar-free or sugar based and can consists of sugars, sucrose, and xylitol. Refer specifically to Page 8 Paragraph 1 and Page 9 Paragraph 3.

17. Regarding claim 12, Hanke discloses that hydrogenated isomaltulose can be included in hard candy confections (Page 1 Paragraph 3).

18. Regarding claims 13-15 and specifically the range of 0.01-0.015% as recited in claim 14 and 0.01-0.05% as recited in claim 15, Hanke discloses that suitable cooling agents include carboxamides, menthol, eucalyptus, menthane esters and methane ethers and mixtures thereof (Page 5 Paragraph 3). Hanke teaches that 3-l-menthoxypropane-1,2 diol and N, 2, 3-trimethyl-2-isopropylbutamide can be utilized from 0.01-15%. Refer specifically to Page 5 Paragraphs 3 and 4, Page 6 (All), Page 7 (All), and Page 8 Paragraph 2.

19. Regarding claims 16-18, Hanke discloses that colorant can be added to the confection. In Example 1 Pages 13-14, Hanke teaches the core and outer layers both contain the same cooler as recited in claims 16 and 17. In Example 2 Pages 14-15, Hanke teaches that only the core contains coloring. Therefore, in Example 2, since the core contains color and the outer layer does not, the core and the outer layer are different colors as recited in claim 18.

20. Regarding claims 19 and 20, Hanke teaches of a confectionary product that includes two distinct and discrete regions, a coolant and flavor region (Abstract) that can be in various forms, including the form as hard candy (Page 3 Paragraph 3). Hanke discloses (Page 3 Paragraphs 3 and 4) that the outer coating or jacket may be continuous and can be comprised of the coolant composition, enrobes the flavor

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composition or the core to create a centre-filled candy. Hanke discloses that the coolant composition or jacket contains 0.01-15%, preferably 0.5-10% of the cooling agent and minor levels of flavoring ingredients (Page 7 Paragraphs 3 and 4, Page 8 Paragraph 1). Hanke discloses that the flavor composition contains preferably 0.4-1.5% flavoring and trace amounts of cooling agents (Page 10 Paragraphs 2 and 3). Hanke, therefore, teaches that the level of cooling agents in the jacketed or outer layer is greater than the level of cooling agents in the core. Hanke discloses that suitable cooling agents include menthol (Page 5 Paragraph 3). Therefore, Hanke discloses that the coolant or jacket level of menthol to the flavor or core level of menthol is greater than 1.5:1 as recited in claim 19 and is greater than 2:1 as recited in claim 20.

Note: As recited in claims 18 and 19, any amount of menthol in the jacket to the amount of menthol in the core could be any value above 1.5:1, including an infinite ratio.

21. Regarding claims 30 and 31, Hanke discloses (Page 3 Paragraphs 3 and 4) that the outer layer or jacket may be continuous, enrobing the entire (i.e. more than 80% or substantially all) core to create a centre-filled candy.

22. Regarding claim 33, Hanke teaches that the coolant composition or outer layer comprises 5-15% of the total composition (Page 13 Paragraph 3).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims 6 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke.

26. Hanke is silent to the range of 0.01-0.4% flavoring as recited in claim 6 and the elongated shape of the candy as recited in claim 34.

27. Regarding claim 6, specifically the range of 0.01-0.4%, Hanke discloses that the product amount of flavoring agent employed is normally a matter of preference subject to factors such as flavor type, base type, and strength desired (Page 10 Paragraph 3). Hanke teaches that it is preferred for the flavoring composition to contain 0.4-1.5% of the flavoring agents and the jacket or coolant composition contains minor levels of flavoring agents (Page 8 Paragraph 1). However, it would have been obvious to one skilled in the art at the time the invention was made to have chosen any amount of flavoring in the confection depending on the preferred flavor type, base, and desired strength in view of Hanke (Page 10 Paragraph 3).

28. Regarding claim 34, the elongated shape of the candy, Hanke is silent to the shape of the hard candy. It would have been obvious to one skilled in the art at the time

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the invention was made to have made the candy any shape depending on the desired mouth feel.

29. Claims 7, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke and in view of Bealin-Kelly (US 6306429 B1).

30. Hanke discloses that the coolant composition or jacket contains preferably 0.5-10% of the cooling agent and that the flavor composition contains trace amounts of cooling agents (Page 10 Paragraph 2 and Page 7 Paragraph 3). Hanke teaches that 3-l-menthoxypropane-1,2 diol and N, 2, 3-trimethyl-2-isopropylbutamide can be utilized from 0.01-15%. Refer specifically to Page 5 Paragraphs 3 and 4, Page 6 (All), Page 7 (All), and Page 8 Paragraph 2.

31. Hanke is silent to the range of 0.001-0.5% cooling agent as recited in claim 7, specifically the range of 0.002-0.01% N, 2, 3-trimethyl-2-isopropylbutamide as recited in claim 14, and the range of 0.005-0.01% 3-l-menthoxypropane-1,2 diol as recited in claim 15.

32. Bealin-Kelly (Bealin) discloses of a throat drop for relief of cough and cold symptoms that comprises of a cooling composition and a warming composition in distinct and discrete regions (Abstract). Bealin discloses that the perceived effect of a physiological cooling agent can be enhanced by incorporating 0.001-10% cooling agent into a confectionary composition, specifically incorporating a cooling agent into first composition which is administered along with a second composition which provides for a delayed release of a cooling or warming agent thus providing a centre-filled

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confectionary composition (Column 1 lines 47-55 and Column 2 lines 27-31). Bealin discloses, Column 4 lines 56-63, that the filling and the shell can be solids, including the form as a hard candy. Bealin discloses, Column 2 lines 20-25 and Column 5 lines 51-53, that the cooling composition (predominantly a cooling agent) can compose the shell or jacket of the confection and that a warming agent, which can include flavoring, can compose the core. Bealin discloses that N, 2, 3-trimethyl-2-isopropylbutamide and 3-l-menthoxypropane-1,2 diol can be utilized as cooling agents of the confectionary product (Column 3 lines 40-58).

33. Regarding claim 7, specifically the range of 0.001-0.5%, Bealin discloses that the cooling composition should be included at a suitable level, including the range of 0.001-0.5% (Column 2 lines 27-31). It would have been obvious to one skilled in the art at the time the invention was made to have modified the candy product as disclosed by Hanke to included the lower range of the cooling agent in view of Bealin. One would have been motivated to do so in order to take advantage of the benefits of the cooling agent in the range of 0.001-0.5%, such as an enhanced perceived effect of the physiological cooling agent as disclosed by Bealin (Column 1 lines 47-55). Because both deal with a hard candy product, one would have a reasonable expectation of success from the combination.

34. Regarding claims 14 and 15 and specifically the range of 0.002-0.01% as recited in claim 14 and 0.005-0.01% as recited in claim 15, Bealin discloses that the cooling compositions, including N, 2, 3-trimethyl-2-isopropylbutamide and 3-l-menthoxypropane-1,2 diol, should be included at suitable levels, including the range of

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0.002-0.01% (Column 2 lines 27-31 and Column 3 lines 40-58). It would have been obvious to one skilled in the art at the time the invention was made to have modified the candy product as disclosed by Hanke to included the lower range of the cooling agents N, 2, 3-trimethyl-2-isopropylbutamide and 3-l-menthoxypropane-1,2 diol, in view of Bealin. One would have been motivated to do so in order to take advantage of the benefits of the cooling agents specifically N, 2, 3-trimethyl-2-isopropylbutamide and 3-l-menthoxypropane-1,2 diol ly, N, 2, 3-trimethyl-2-isopropylbutamide and 3-l-menthoxypropane-1,2 diol in the range of 0.002-0.01%, such as an enhanced perceived effect of the physiological cooling agent as disclosed by Bealin (Column 1 lines 47-55). Because both deal with a hard candy product, one would have a reasonable expectation of success from the combination.

35. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke and in view of Klacik et al. (US 4452825).

36. Hanke teaches as the hard candy product as homogeneous, however is silent to the hard candy product as clear (Page 10 Paragraph 3).

37. Klacik et al. (Klacik) discloses that it is desirable to have traditional or ordinary properties of a candy when making a candy, such as a clear composition and good texture (Column 1 lines 5-13). It would have been obvious to one skilled in the art at the time the invention was made to have modified the hard candy composition as disclosed by Hanke to include a clear composition in view of Klacik. One would have been motivated to do so because a clear composition is one of the traditional properties of

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candy that is desired (Klacik Column 1 lines 5-13). Because both deal with the production of hard candies, one would have a reasonable expectation of success from the combination.

38. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke and in view of Linden and Lorient (New Ingredients in Food Processing).

39. Hanke is silent to 0.001-2% of a high intensity sweetener, such as aspartame in the confection, as recited in claims 35 and 36.

40. Linden and Lorient (Linden) discloses that aspartame has a sweetening power 200 times that of sucrose (Page 231).

41. Regarding claims 35 and 36, it is would have been obvious to modify the confection as taught by Hanke to include a bulk sweetener, such as aspartame as taught by Linden. One would have been motivated to add aspartame in order to get the same intensity of sweetness at a lower dosage than required by sucrose. It would have been obvious that the range of the bulk sweetener added would depend upon the bulk sweetener chosen and the amount of sweetness desired.

Conclusion

42. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

43. US 4762719 discloses of a powdered filled, hard candy cough drop that contains a cooling agent in both the inner and outer layers so that discernable vaporization is felt.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly Mahafkey whose telephone number is (571) 272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



11/14/05

Kelly Mahafkey
Examiner
Art Unit 1761

Steve Weinstein
STEVE WEINSTEIN 1761
PRIMARY EXAMINER
11/14/05